

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-0188001	Application No. 10/09/367,950
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant Tommy Ekstrom	
		Filing Date August 18, 1999	Group Art Unit 1617
(37 CFR §1.98(b))			

### U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
/JK/	A1	5,674,860	10/2007	Carling et al.			
↓	A2	5,972,919	10/1999	Carling et al.			
	A3	6,030,604	02/2000	Trofast			
	A4	6,227,862	08/2001	Giardina et al.			
/JK/	A5	6,598,603	07/2003	Andersson et al.			

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
/JK/	A6	9703407-8		Sweden				
/JK/	A7	EP 1 014 993	07/05/2000	Europe				

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	No Date!!	Document
	A8		Additive effects of Budesonide and Formoterol in Reducing Severe Asthma Exacerbations Over 12 Months, O'Byrne et al. on behalf of international study group and Astra Draco AB, Lund Sweden
/JK/	A9		"American Thoracic Society: Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease," <i>Am. J. Respir. Care Med.</i> 152:S77-S121 (1995)
↓	A10		"Analysis of DIN-LINK Co-prescription Records for Inhaled Steroids and Long-Acting Beta Agonists in the Period 1990-1998" pages 1-2, appendices A and B
	A11		"Atemstillstand" <i>Psyhyrembel Klinisches Wörterbuch</i> (2002) (in German)
	A12		Auffarth et al., "Effects of inhaled budesonide on spirometric values, reversibility, airway responsiveness, and cough threshold in smokers with chronic obstructive lung disease" <i>Thorax</i> 46:372-377 (1991)
	A13		Barnes, "Inhaled steroids in COPD" <i>The Lancet</i> 351:766-767 (1998)
	A14		Barnes et al., "Chronic obstructive pulmonary disease: molecular and cellular mechanisms," <i>Eur. Respir. J.</i> 22:672-688 (2003)
	A15		Basic Reference Manual, vol. 1, revised ed. of 1988, issued by IMS International
	A16		Boyd et al., "An Evaluation of Salmeterol in the Treatment of Chronic Obstructive Pulmonary Disease (COPD)," <i>Eur. Resp. J.</i> 10:815-821 (1997)
	A17		"Bronchodilators and anti-inflammatories," <i>Monthly Index of Medical Specialities (MIMS)</i> 242-256 (09/1997)
/JK/	A18		Buist, "Definitions," in <i>Asthma and Chronic Obstructive Pulmonary Disease</i> , Barnes et al. eds., Acad. Press, pp. 3-6 (2002)

Examiner Signature /Jennifer Kim/	Date Considered 09/30/2008
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/JK/	A19	Burge et al. "Randomised, double blind, placebo controlled study of fluticasone propionate in patients with moderate to severe chronic obstructive pulmonary disease: the ISOLDE trial," British Med. J. 320:1297-1303 (2000)
	A20	Calverley et al., "Maintenance therapy with budesonide and formoterol in chronic obstructive pulmonary disease," Eur. Respir. J. 22:912-919 (2003)
	A21	Cazzola et al., "Effect of salmeterol and formoterol in patients with chronic obstructive pulmonary disease", Pulmonary Pharmacology, 1994, 7/2, pages 103-107.
	A22	Compendium Suisse des Medicaments, 15 <sup>th</sup> Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 2-3, 419-429, 866 (in French).
	A23	Compendium Suisse des Medicaments, 18 <sup>th</sup> Ed. 1997, Ed., compiled June 1996, pages 5, 849-851 and 1635-1636 (in French).
	A24	C. Wyser et al., "Neue Aspekte in der Behandlung des Asthma bronchiale und chronisch obstruktiver Lungenkrankheiten", 1997, Schweiz Med Wochenschr, Volume 127, pages 885-890.
	A25	Davies et al., "Oral corticosteroid trials in the management of stable chronic obstructive pulmonary disease," Q. J. Med. 92:395-400 (1999)
	A26	Declaration of Professor N.B. Pride dated August 4, 2004
	A27	D.C. Flenley, "Today's Treatment of Airway Obstruction... and Tomorrow's?", Respiration, pages 4-9 (1989).
	A28	"Disorders of the Airways," Current Medical Diagnosis and Treatment 1997 36th ed. pages 241-255, Stamford, CT: Appleton and Lange (1997)
	A29	Dompeling et al., "Slowing the deterioration of Asthma and Chronic Obstructive Pulmonary Disease Observed during Bronchodilator Therapy by Adding Inhaled Corticosteroids," Ann. Intern. Med. 118(10):770-778 (1993)
	A30	Engel et al., "A trial of inhaled budesonide on airway responsiveness in smokers with chronic bronchitis" Eur. Respir. J. 2:935-939 (1989)
	A31	Fabbri et al., "Global Strategy for the Diagnosis, Management and Prevention of COPD: 2003 update" Eur. Respir. J. 22:1-2 (2003)
	A32	Flenley, "Chronic Obstructive Pulmonary Disease," Disease-A-Month 34:549-599 (1988)
	A33	"Foradil" Compendium Suisse des Medicaments, Supplement 1a pages 7-8 (1991) (in French)
	A34	"Foradil," Compendium Suisse des Medicaments, 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 419-420, 866 (in French)
	A35	"Foradil," Compendium Suisse des Medicaments, 18th Ed. 1997, compiled June 1996, pages 849-850 and 1635 (in French)
	A36	"Foradil" Patient information leaflet, published by IKS, Switzerland (12/1990) (in French)
	A37	"Foradil" MIMS-Monthly Index of Medical Specialties January 10 (1996)
	A38	Gibson et al., Respiratory Medicine Table of contents (2002)
/JK/	A39	"GOLD: Global Initiative for Chronic Obstructive Lung Disease," Executive Summary; National Institutes of Health, National Heart Lung and Blood Institute, NIH Publication No. 2701A, pages 1-30 (03/2001)

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/JK/	A40	"GOLD: Global Initiative for Chronic Obstructive Lung Disease; Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease," based on April 1998 NHLBI/WHO Workshop, pages 1-100 (2004 Update)
	A41	Jackevicius et al., "Prehospitalization Inhaled Corticosteroid Use in Patients With COPD or Asthma" <i>Chest</i> 111:296-302 (1997)
	A42	Jeffery "Structural and inflammatory changes in COPD: a comparison with asthma" <i>Thorax</i> 53:129-136 (1998)
	A43	Keatings et al., "Effects of Inhaled and Oral Glucocorticoids on Inflammatory Indices in Asthma and COPD" <i>Am. J. Respir. Crit. Care Med.</i> 155:542-548 (1997)
	A44	Kerstjens et al., "A Comparison of Bronchodilator Therapy with or without Inhaled Corticosteroid Therapy for Obstructive Airways Disease," <i>New Eng. J. Med.</i> 327:1413-1419 (1992)
	A45	Leff et al., "Therapeutic Regimens in Chronic Obstructive Pulmonary Disease," <i>Pulmon. Crit. Care Pharmacol. Therapeut. Ch.</i> 86:837-844 (1996)
	A46	Minutes of the May 6, 2008 oral proceedings before the European Patent Office Technical Board of Appeal in the opposition against EP 1014993 (4 pages)
	A47	Nederlands Tijdschrift voor Geneeskunde "Opportunistic lung infection in patients with chronic obstructive pulmonary disease", 1996 140/2 pages 94-98 ISSN: 0028-2162 CODEN: NET JAN
	A48	New Ethicals Catalogue, December 1990, No. 3, p. 50
	A49	Niewoehner et al., "Effect of Systemic Glucocorticoids on Exacerbations of Chronic Obstructive Pulmonary Disease" <i>New Eng. J. Med.</i> 340(25):1941-1947 (1999)
	A50	Norman, "COPD: New Developments and Therapeutic Opportunities" <i>Drug News Perspect.</i> 11(7):431-437 (1998)
	A51	Pauwels et al., "Long-Term Treatment with Inhaled Budesonide in Persons with Mild Chronic Obstructive Pulmonary Disease Who Continue Smoking" <i>N. Eng. J. Med.</i> 340:1948-1953 (1999)
	A52	Pauwels, "COPD: The Scope of the Problem in Europe" <i>Chest</i> 117:332S-335S (2000)
	A53	Pearson et al., "British Thoracic Society Guidelines for Treatment of COPD" <i>Thorax</i> 52 (Suppl. 5):S1-S28 (1997)
	A54	Postma et al., "Rationale for the Dutch Hypothesis* Allergy and Airway Hyperresponsiveness as Genetic Factors and Their Interaction with Environment in the Development of Asthma and COPD", <i>Chest</i> , 126: 96S-104S (2004).
	A55	Postma, "Inhaled therapy in COPD: what are the benefits?" <i>Respiratory Medicine</i> 85:447-449 (1991)
	A56	"Pulmicort" ABPI Data Sheet Compendium, p. 146-147 (1995/1996)
	A57	Rabe, "Combination therapy for chronic obstructive pulmonary disease; one size fits all?" <i>Eur. Respir. J.</i> 22:874-875 (2003)
	A58	Renkema et al., "Effects of long-term treatment with corticosteroids in COPD," <i>Chest</i> , 1996, Vol. 109, No. 5, abstract. AN 1996: 325104.
	A59	Renkema et al. "Key to the World's Chemical Literature", Vol. 126, No. 20 (1997), CA (Chemical Abstracts) No. 259329
	A60	Roberts et al., "Which patients are prescribed inhaled anti-asthma drugs?" <i>Thorax</i> 49(11):1090-1095 (1994)

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/JK/	A61	Sauders Manual of Medical Practice. Rake! 1996.
	A62	Schultze-Werninghaus, "Multicenter 1-Year Trial on Formoterol, a New Long-Acting $\beta_2$ -Agonist, in Chronic Obstructive Airway Disease," <i>Lung Suppl</i> :83-89 (1990)
	A63	Siafakas <i>et al.</i> , "Optimal Assessment and Management of Chronic Obstructive Pulmonary Disease (COPD)," <i>Eur. Respir. J.</i> 8:1398-1420 (1995)
	A64	Soriano <i>et al.</i> , "The Proportional Venn Diagram of Obstructive Lung Disease* Two Approximations From the United States and the United Kingdom", <i>Chest</i> 124: 474-481 (2003).
	A65	Soriano <i>et al.</i> , "Inhaled Corticosteroids with/Without Long-Acting $\beta$ -Agonists Reduce the Risk of Rehospitalization and Death in COPD Patients," <i>Am. J. Respir. Med.</i> 2:67-74 (2003)
	A66	Stalenheim <i>et al.</i> , "Efficacy and Tolerance of a 12-Week Treatment with Inhaled Formoterol in Patients with Reversible Obstructive Lung Disease," <i>Respiration</i> 61:305-309 (1994)
	A67	Statutory Declaration of Charles Richard William Beasley
	A68	Stedman's Medical Dictionary, 25 <sup>th</sup> ed., Baltimore: Williams and Wilkins; page 428
	A69	Szafranski <i>et al.</i> , "Efficacy and safety of budesonide/formoterol in the management of chronic obstructive pulmonary disease" <i>Eur. Respir. J.</i> 21:74-81 (2003)
	A70	The Merck Manual, sixteenth Edition, 1992, pages 658-659
	A71	Treschel, AM Conference Report, A new long-acting beta-stimulator
	A72	Van Schayck <i>et al.</i> , "Do patients with COPD benefit from treatment with inhaled corticosteroids?" <i>Eur. Respir. J.</i> 9:1969-1972 (1996)
	A73	Van Andel <i>et al.</i> , "Analysis of Inhaled Corticosteroid and Oral Theophylline Use Among Patients With Stable COPD from 1987 to 1995" <i>Chest</i> 115:703-707 (1999)
	A74	Vestbo <i>et al.</i> , "Long-term effect of inhaled budesonide in mild and moderate chronic obstructive pulmonary disease: a randomised controlled trial," <i>Lancet</i> 353:1819-1823 (1999)
	A75	Vestbo <i>et al.</i> , "Update on the "Dutch hypothesis", for chronic respiratory disease", <i>Thorax</i> 53(Suppl.2), S15-S19 (1998).
	A76	Watson <i>et al.</i> , "Failure of Inhaled Corticosteroids to Modify Bronchoconstrictor or Bronchodilator Responsiveness in Middle-Aged Smokers with Mild Airflow Obstruction" <i>Chest</i> 101:350-355 (1992)
	A77	Weiner <i>et al.</i> , "Inhaled Budesonide Therapy for Patients with Stable COPD," <i>Chest</i> 108:1568-1571 (1995)
/JK/	A78	Written decision of the European Patent Office Technical Board of Appeal in the opposition against EP 1014993, dated May 6, 2008 (17 pages).

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